REMARKS

The Examiner is thanked for carefully reviewing the present application. The present amendment is in response to the Office Action mailed on Jane 12, 2009 regarding claims 1-9, 11-16, and 18-19. The applicants have thoroughly reviewed the outstanding Office Action including the Examiner's remarks and the references cited therein. The following remarks are believed to be fully responsive to the Office Action and render all claims at issue patentably distinguishable over cited references.

Claims 1 and 9 are currently amended, wherein claims 7-8 are added into claim 1 and cancelled, claims 18-19 are added into claim 9 and cancelled, claims 7, 8, 18 and 19 are cancelled, and claims 6, 10 and 17 are previously cancelled, while claims 1 and 9 are further added with a limitation of "a first film is a membrane excluding hollow fibers of hollow fiber contactor (HFC) and ..." to limit claims 1 and 9 and to distinguish from citation Bomberger '809 et al. (US 20030150809).

Applicants respectfully submit that no new matter has been added and that the originally filed specification, drawings and claims fully support the amendments.

Claim Rejections Under 35 U.S.C. 103 (a)

Examiner has rejected claims 1-5, 9 and 11-16 as being unpatentable over **Bomberger '809** et al. (US 20030150809) in view of **Bomberger '776** et al. (US 20060000776) in view of **Matkovich** et al. (US 5252222) in view of **Papillon; Jean** et al. (US 5348533) in view of **Cham** et al. (US 4895558). These grounds of rejection are respectfully traversed.

When applying 35 U.S.C. §103, the following tenets of patent law must be adhered to:

(A) The claimed invention must be considered as a whole;

(B) The references must be considered as a whole and must suggest the desirability and

thus the obviousness of making the combination;

(C) The references must be **viewed without the benefit of impermissible hindsight vision afforded by the claimed invention**; and

(D) Reasonable expectation of success is the standard with which obviousness is determined.

Hodosh v. Block Drug Co., Inc., 786 F.2d 1136, 1143 n.5, 229 USPQ 182, 187 n.5 (Fed. Cir. 1986). (MPEP §2141)

If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is **no suggestion or motivation** to make the proposed modification. In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984) (MPEP 2143)

The PTO further specifies in MPEP §2142 that:

The examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness. If the examiner does not produce a prima facie case, the applicant is under no obligation to submit evidence of non-obviousness.

Applicants can **not** agree that the claims 1 and 9 are unpatentable over **Bomberger '809** in view of **Bomberger '776**, **Matkovich**, **Papillon** and **Cham**. The reason is that a person skilled in the art can **not easily** combine all of these 5 citations to obtain the whole claimed invention of claims 1 and 9, while these 5 citations belong to **different device fields** and no suggestion or motivation to make the proposed modification as described by the Official Action.

As shown in Fig.1, claim 1 of the claimed invention recites that an in-vitro blood plasma lipids filtering method briefly comprises the steps of: collecting blood; separating blood plasma by the blood separating device, wherein the blood plasma enters the pre-filtered blood plasma bag

including an automatic weight or volume detection device; flushing the blood plasma lipids filtering device by the saline solution treatment bag before filtering, wherein the flushed saline solution flows into the waste saline solution bag; controlling pressure of the separated blood plasma; filtering out lipids by the blood plasma lipids filtering device **excluding hollow fiber contactor (HFC)** comprising multi-layers of thin film membranes, wherein at least a first film having filter aperture pores of about 0.3 to 0.65 microns and made of a lipid absorptive material for filtering out lipids of the separated blood plasma, a second film having filter aperture pores of about 0.3 microns for filtering out bacterium and chyle-lipoprotein, and a third film having filter aperture pore of about 0.2 microns and made of nylon as a base material for filtering out foreign particles generated from the first and second filtering processes, wherein the foreign particles include thin film wood-pulp material or adsorptive particles, **wherein at least one additional first film is further interposed between the second and third films, and wherein the lipid absorptive material of the first film and the additional first film comprises silicon oxide pellets**; collecting the filtered blood plasma by the post-filtered blood plasma bag; controlling the temperature of the filtered blood plasma; and feeding the filtered blood plasma back to the blood. After the amendment, all connection relationships, element functions and step orders of all steps are limitations of claim 1.

Regarding claim 1, **Bomberger '809** only discloses systems and methods using multiple solvents for the removal of lipids from fluids, but **the hollow fibers 20 of HFC 18 is not used to remove lipids**. According to paragraph [0101]-[0102], **Bomberger '809** discloses that each hollow fiber 20, as shown in FIG. 4, is a cylindrical tube having a small diameter and is formed from a membrane having **pores 26 sized to allow** gases and **liquids to pass through the membrane**. Pores 26 may have a diameter within the range of between about 5 kilodaltons and about 500 kilodaltons or between about 3 nanometers and about 300 nanometers. Varying the size

of pores 26 can allow either more or less materials to pass through pores 26. Hollow fibers 20 are positioned in HFC 18 so that their longitudinal axes are generally parallel to the longitudinal axis of the HFC 18. **Pores 26 need only be large enough to allow the first and second extraction solvents** and a gas to diffuse through pores 26 **and for lipids to diffuse through pores 26 and into the solvents**. ..... **The lipids that may have been solubilized by the action of the solvents** diffuse into the solvent in the pores 26 at the interface. **The lipids continue to diffuse through pores 26 until the lipids are swept away by the solvent flowing through HFC 18 on the shell side 22 of the lumens**. If a hydrophilic material is used to form hollow fibers 20, pores 26 fill with fluid, and the solvent does not fill pores 26. The lipids then diffuse through pores 26. Hence, it should be noted that **the hollow fibers 20 of HFC 18 is actually used to allow lipids to diffuse through pores 26 and into the solvents, and the pore 26 must be only large enough for lipids to diffuse therethrough, while the lipids is actually swept away by being solubilized by the action of the solvents, but not by pores 26 of the hollow fibers 20 of HFC 18 itself**. Moreover, because the diameter of the pores 26 is within the range of between between about 3 and 300 nanometers and allows lipids to diffuse through pores 26, the solubilized type of lipid diffusing through pores 26 must be different from the filtered type of lipids being filtered out by the lipid absorptive material of the first film having filter aperture pores of about 0.3 to 0.65 microns as claimed in claim 1 of the present invention. Now, amended claim 1 of the present invention is added with a limitation of "a first film is a membrane excluding hollow fibers of hollow fiber contactor (HFC) and ..." to exclude hollow fibers 20 of HFC 18 of Bomberger '809. In addition, Bomberger '809 does **not** disclose that at least one **additional first film is further interposed between the second and third films**, and the lipid absorptive material of the first film and the additional first film comprises **silicon oxide pellets which are apparently different form hollow fibers of HFC**. As a result, the systems and methods of Bomberger '809 is a multi-phase

apparatus using multiple solvents and exactly exists the foregoing differences from the present invention (other differences can be viewed in the remarks of the response of RCE), while **Bomberger '809** also does not have the motivation of combining with other 4 citations.

Regarding claim 1, **Bomberger '776** only discloses hollow fiber contactor (HFC) systems for removal of lipids from fluids, wherein a fluid source 14 may be composed of a plasmapheresis bag for containing a fluid (paragraph [0082]) and a saline fluid source 21 for containing a saline fluid (paragraph [0083]). However, Bomberger '776 does **not** disclose that at least one **additional first film is further interposed between the second and third films**, and the lipid absorptive material of the first film and the additional first film comprises **silicon oxide pellets which are different form hollow fibers of HFC**. In addition, the systems of Bomberger '776 is different from the systems and methods of **Bomberger '809** (a multi-phase apparatus using multiple solvents) or the present invention, and also does not have the motivation of combining with **Bomberger '809**, wherein such combination would not lead to Applicants' disclosed and claimed invention having a first film being membrane excluding hollow fibers of hollow fiber contactor (HFC).

Regarding claim 1, **Matkovich** discloses a filter for parenteral systems and method of using thereof, however, the filter device and method of Matkovich is used to treat parenteral nutrient fluid **containing a lipid for administration (lipid is remained in parenteral nutrient fluid after filtering)**, but **not** applied to the technical filed for **removing lipids** from blood plasma (lipids is removed after filtering). In fact, the filter device and method of Matkovich is in a technical field obviously different from the field of Bomberger '809 or the present invention. Actually, the filter device of Examples 3 and 5 of Matkovich includes a prefilter (second filter) with a pore rating of about 0.2 um and a hydrophilic nylon membrane (third filter) with a pore rating of about 0.65 um (column 8, lines 32-41; column 7, lines 54-58), however the prefilter and

hydrophilic nylon membrane are **not** used to remove **bacterium and chyle-lipoprotein** from parenteral nutrient fluid or remove **foreign particles including thin film wood-pulp material or adsorptive particles** generated from parenteral nutrient fluid. Especially, the pore rating of about **0.2 um** of the prefilter (second filter) is different from the aperture pores of about 0.3 microns of second film claimed in amended claim 1 of the present invention, while the pore rating of about **0.65 um** of the hydrophilic nylon membrane (third filter) is quite different from the aperture pores of about 0.2 microns of third film claimed in amended claim 1 of the present invention.

Meanwhile, **Bomberger '809** discloses HFC 18 comprises hollow fiber 20 (first filter) having pores 26 between 3 nm (i.e. 0.003 um) and 300 um (i.e. 0.3 um) (paragraph [0101]), but the hollow fibers 20 of HFC 18 of Bomberger '809 is actually used to **allow** lipids to diffuse through pores 26 and into the solvents, while the lipids is actually swept away by being solubilized by the action of the solvents, but not by pores 26 of the hollow fibers 20 of HFC 18 itself. Especially, it should be noted that the pore size (0.003 um-0.3 um) of the hollow fiber 20 (first filter) of **Bomberger '809** is **smaller** than the pore rating (0.2 um) of the prefilter (second filter) of **Matkovich**, which is **further smaller** than the pore rating (0.65 um) of the hydrophilic nylon membrane (third filter) of Matkovich. In comparison, in amended claim 1 of the present invention, the aperture pore (0.3 um–0.65 um) of the first film is **greater** than the aperture pore (0.3 um) of the second film, which is **further greater** than the aperture pore (0.2 um) of the third film. Therefore, the pore size arrangement of Bomberger '809 and Matkovich is quite different from that of the present invention. Moreover, **Matkovich** does not suggest any desirability to combine with **Bomberger '809 and '776 due to quite different technical fields**, wherein such combination would not lead to Applicants disclosed and claimed invention having a first film being membrane excluding hollow fibers of hollow fiber contactor (HFC), having at least one additional first film further interposed between the second and third films, and having the lipid absorptive material of

the first film and the additional first film comprising **silicon oxide pellets which are different form hollow fibers of HFC**.

Regarding claim 1, **Papillon** discloses a pheresis apparatus which is in a technical field obviously different from the field of Bomberger '809, Bomberger '776, Matkovich or the present invention. Papillon only teaches that a centrifuge 40 is comprised of a stationary part 12 and a rotatable part (bowl 10) (column 3-4, lines 65-9) and a digital weigher W2 is attached to plasma bag 18 to provide a signal to the processor 20 indicating the volume of fluid collected in the bags, but the weigher W2 and plasma bag 18 are in downstream of the centrifuge 40 which is not used for filtering out lipids from blood. The differences between **Matkovich** and claim 1 of the present invention the can be viewed in the remarks of the response of RCE, the pheresis apparatus of Papillon is different from the present invention, while **Papillon** also does not have the motivation of combining with **Bomberger '809 and '776 and Matkovich due to quite different technical fields**, wherein such combination would not lead to Applicants disclosed and claimed invention having a first film being membrane excluding hollow fibers of hollow fiber contactor (HFC), having at least one additional first film further interposed between the second and third films, and having the lipid absorptive material of the first film and the additional first film comprising **silicon oxide pellets which are different form hollow fibers of HFC**.

Regarding claim 1, **Cham** discloses an autologous plasma delipidation using a continuous flow system, wherein the delipidated plasma is drawn by the fluid replacement pump to be mixed with the red blood cells (a **replacement fluid** may be added to the plasma to overcome any loss in bulk of the plasma during the delipidation and separation steps)(column 8, lines 40-44) and the mixture passes through a vein monitor and is fed to a first disposable centrifugal separator where the blood is separated into red blood cells, plasma and **waste products** (the latter being collected in a **waste bag**) (column 8, lines 8-18). The differences between **Cham** and claim 1 of the present

invention the can be viewed in the remarks of the response of RCE, the autologous plasma delipidation of Cham is different from the present invention, while **Cham** also does not have the motivation of combining with **Bomberger '809 and '776, Matkovich and Papillon** **due to quite different technical fields**, wherein such combination would not lead to Applicants disclosed and claimed invention having a first film being membrane excluding hollow fibers of hollow fiber contactor (HFC), having at least one additional first film further interposed between the second and third films, and having the lipid absorptive material of the first film and the additional first film comprising **silicon oxide pellets which are different form hollow fibers of HFC**.

Accordingly, it is therefore respectfully submitted that the Office Action fails to establish a prima facie case of obviousness under §103 with respect to claim 1 of the claimed invention; and also fails to suggest the desirability for combining Bomberger '776 and '809, Matkovich, Papillon and Cham to teach claim 1 of the claimed invention.

Claim Rejections Under 35 U.S.C. 103 (a)

Examiner has rejected claims 8 and 19 as being unpatentable over **Bomberger '809**, **Bomberger '776**, **Matkovich**, **Papillon** and **Cham**, and further in view of **Foltz** et al. (US 5401466). These grounds of rejection are respectfully traversed.

Regarding claim 8, all elements and function thereof are added into **amended claim 1**, and claim 8 is cancelled now. Regarding claim 19, all elements and function thereof are added into **amended claim 9**, and claim 19 is cancelled now. The amended claim 1 (or 9) is unobvious over the combination of these prior arts of record.

Regarding amended claim 1, **Foltz** only discloses a device for the direct measurement of low density lipoprotein cholesterol, wherein a second layer designed to remove **very low density lipoproteins (VLDL)/chylomicrons** from the blood, and a third layer containing means for

quantitative cholesterol detection (abstract). Apparently, because **very low density lipoproteins (VLDL)/chylomicrons belong to lipoprotein or chyle-lipoprotein** but not so-called lipids, the filter of **Foltz** is **not** the same as the lipid absorptive material of the **first film** and the **additional first film** of the present invention for filtering out **lipids** of the separated blood plasma and comprising **silicon oxide "pellets" which are different form hollow fibers of HFC**. In addition, the device of **Foltz** is a **test device** for the direct determination of low density lipoproteins cholesterol, and the device of **Foltz** apparently belongs to different device field from that of the systems and methods of **Bomberger '809** (a multi-phase apparatus using multiple solvents), other citations or the present invention. Furthermore, **Foltz** further does not have the motivation of combining with **Bomberger '809**, **Bomberger '776**, **Matkovich**, **Papillon** and **Cham**, wherein such combination would not lead to Applicants' disclosed and claimed invention having a first film being membrane excluding hollow fibers of hollow fiber contactor (HFC), having at least one additional first film further interposed between the second and third films, and having the lipid absorptive material of the first film and the additional first film comprising **silicon oxide pellets which are different form hollow fibers of HFC**..

Accordingly, it is therefore respectfully submitted that the Office Action fails to establish a prima facie case of obviousness under §103 with respect to amended claim 1 (now added with claims 7-8 and the limitation "excluding hollow fibers of HFC") of the claimed invention; and also fails to suggest the desirability for combining **Bomberger '809**, **Bomberger '776**, **Matkovich**, **Papillon**, **Cham** and **Foltz** to teach amended claim 1 of the claimed invention since a person skilled in the art can **not easily** combine all of these 6 citations to obtain the whole claimed invention of claims 1, while these 6 citations belong to **different device fields** and no suggestion or motivation to make the proposed modification as described by the Official Action.

In addition, insofar claims 2-5 depend upon amended claim 1. These claims add further

limitations thereto. Thus, claims 2-5 of the present application are also unobvious over the prior art of record. Accordingly, Applicants respectfully request that the section 103(a) rejections be withdrawn.

Besides, claim 9 is amended based on the same limitations as that of amended claim 1, so that the amended claim 9 is also unobvious over the prior art of record. Meanwhile, insofar claims 11-16 depend upon amended claim 9. These claims add further limitations thereto. Thus, claims 11-16 of the present application are also unobvious over the prior art of record. Accordingly, Applicants respectfully request that the section 103(a) rejections be withdrawn.

CONCLUSION

In light of the above amendments and remarks, Applicants respectfully submit that all pending claims as currently presented are in condition of allowance and hereby respectfully request reconsideration.

Respectfully submitted,

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